



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 29, 2016

Michael Braverman
Manager, Biopesticide and Organic Support Program
IR-4 Project, Rutgers University
500 College Road East, Suite 201W
Princeton, New Jersey 08540

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment - To
remove expiration date based on acceptable storage stability data
Product Name: *Aspergillus flavus* AF36 Prevail
EPA Registration Number: 71693-2
Application Date: May 4, 2016
OPP Decision Number: 517506

Dear Dr. Braverman:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval satisfies a term that was imposed at the time of registration. You continue to be subject to other existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Page 2 of 2
EPA Reg. No. 71693-2
OPP Decision Number: 517506

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Michael Glikes of my team by phone at (703)305-6231 or via email at glikes.michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

Alan Reynolds, Team Leader
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Aspergillus flavus AF36 Prevail

COTTON: FOR USE ONLY IN THE STATES OF ARIZONA, TEXAS AND CALIFORNIA (Imperial, Riverside and San Bernardino counties only)

CORN: FOR USE ONLY IN THE STATES OF ARIZONA AND TEXAS

PISTACHIO: FOR USE ONLY IN THE STATES OF CALIFORNIA, ARIZONA, TEXAS AND NEW MEXICO

For displacing aflatoxin-producing fungi

Aspergillus flavus AF36 is a strain of *Aspergillus flavus* that occurs naturally. When applied to cotton just prior to first bloom, to corn from the 7 leaf stage (V7) until silking, or to pistachio from late May through early July. *Aspergillus flavus AF36* competes with strains of *Aspergillus flavus* that produce large amounts of aflatoxin and, in doing so, limits the amount of these high aflatoxin producers that become associated with the crop.

Active ingredient: <i>Aspergillus flavus</i> strain AF36*	0.0008%
Other inert ingredients:	99.9992%
Total:	100.0000%

* Contains a minimum of 3,000 CFU/gram in the End-Use Product

KEEP OUT OF REACH OF CHILDREN

CAUTION

First Aid	
IF INHALED:	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
IF IN EYES:	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

SEE PRECAUTIONARY STATEMENTS BELOW AND ON OTHER PANEL

EPA Registration No.: 71693-2
EPA Establishment No.: 71693-AZ-001

Arizona Cotton Research and Protection Council
3721 E. Wier Avenue
Phoenix, Arizona 85040

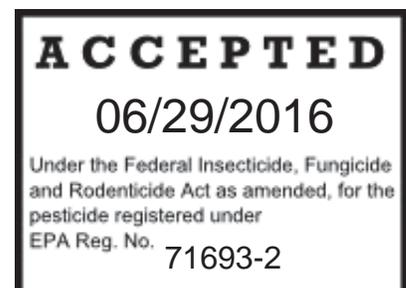
NET WEIGHT: 50 lb bags, 1000-3000 lb in bulk bags or boxes

BATCH CODE:

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing dust. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.



PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- Protective eyewear.
- A NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)
- Long-sleeved shirt and long pants.
- Waterproof gloves.
- Shoes and socks.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation. Read all label directions before using.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water) is coveralls, waterproof gloves, shoes, socks, goggles, and a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95.

GENERAL INFORMATION

Aspergillus flavus AF36 is a naturally occurring fungus that displaces aflatoxin-producing fungi within the crop environment. AF36 has been shown to reduce aflatoxin both in laboratory studies and commercial field studies.

PRODUCT INFORMATION

Aspergillus flavus AF36 is for application to cotton, corn and pistachio to displace aflatoxin-producing strains of *Aspergillus flavus*.

Aspergillus flavus AF36 is a living fungus growing on grain, which serves as both a carrier and a nutrient source. After application and once the colonized grain is exposed to sufficient moisture (this may occur at irrigation), *Aspergillus flavus* AF36 will grow out and the grain will be covered with green spores. This growing fungus will first appear as white fuzz and later as green fuzz. The green spores will eventually be spread to the crop by wind and insects in the same manner that aflatoxin-producing fungi are spread.

USE PRECAUTIONS

Do not apply as a tank mixture with fertilizers, insecticides, or fungicides. Apply *Aspergillus flavus* AF36 only when the potential for drift to adjacent, sensitive areas (e.g., residential areas, bodies of water, known habitat for threatened or endangered species, nontarget crops) is minimal.

Aspergillus flavus AF36 may be applied to irrigated crops.

APPLICATION INSTRUCTIONS

Ground Application: COTTON

1. Apply *Aspergillus flavus* AF36 to the surface of the soil under the plant canopy with a tractor-mounted, granular applicator. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to furrows.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied from late May through June, prior to first bloom. Make a single application during the last cultivation before bloom.
4. Furrow irrigating the crop with at least 2 inches of water within 3 days after application of *Aspergillus flavus* AF36 will provide best results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre of cotton (per 13,000 linear feet based on 40-inch rows).

Ground Application: CORN

1. Apply *Aspergillus flavus* AF36 directly to the soil or under the plant canopy after last cultivation with a tractor-mounted, granular applicator. Make a single application from the V7 growth stage until emergence of the silks from the husk. Cultivation must be completed before application. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to areas without corn.
3. Rain or irrigation within 3 days of application of *Aspergillus flavus* AF36 will improve results.
4. Use 10 lbs of *Aspergillus flavus* AF36 per acre of corn (per 13,000 linear feet based on 40-inch rows).

Ground Application: PISTACHIO

1. Apply *Aspergillus flavus* AF36 to the surface of the soil under the plant canopy with a granular applicator. DO NOT COVER THE APPLIED PRODUCT WITH SOIL.
2. Adjust the applicator to optimize delivery of *Aspergillus flavus* AF36 under the canopy and to minimize delivery of *Aspergillus flavus* AF36 to areas that do not get wet.
3. *Aspergillus flavus* AF36 has been shown to be effective when applied in Pistachio from late May through early July.
4. Rain or irrigation within 3 days after application of *Aspergillus flavus* AF36 will improve results.
5. Use 10 lbs of *Aspergillus flavus* AF36 per acre; a single application should be made each year.

Aerial Application: COTTON, CORN, PISTACHIO

1. Apply by air at the appropriate rate, timing, and frequency as described for ground applications.
2. Cultivation after application may diminish efficacy.
3. Rain or irrigation within 3 days after application of *Aspergillus flavus* AF36 will improve results.

Aspergillus flavus AF36 is a naturally occurring fungus that displaces aflatoxin-producing fungi within the crop environment. *Aspergillus flavus* AF36 must grow and produce spores on the grain to be effective. The product performs best when applied under warm conditions to moist soil or just prior to rain or irrigation. AF36 has been shown to reduce aflatoxin both in laboratory studies and commercial field studies.

STORAGE AND DISPOSAL

DO NOT CONTAMINATE WATER, FOOD, OR FEED BY STORAGE AND DISPOSAL.

PESTICIDE STORAGE: Store dry. Do not expose to relative humidity greater than 80% prior to use. This product contains a living organism that must be alive to work. Do not store under extreme conditions. Do not freeze. Do not expose to temperatures above 50° C (122° F).

PESTICIDE DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING:

Paper Bags (50 lb) – Nonrefillable container. Do not reuse or refill container. Completely empty bag into application equipment. Then offer for recycling if available or dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

Returnable/Refillable Bulk Bags and Boxes (1000-3000 lb) – Refillable container. Return empty container to point of purchase. Refill this container with *Aspergillus flavus* AF36 only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, completely empty bag (or box) into application equipment. Then offer for recycling if available or dispose of empty bag (or box) in a sanitary landfill, or by incineration, or by other procedures allowed by state and local authorities.

WARRANTY STATEMENT

To the extent consistent with applicable law, user assumes all risks of use, storage, and handling of this material not in strict accordance with directions provided on this label.